

REMARKS

This paper is responsive to the Office Action mailed September 8, 2009. Upon entry of the foregoing amendments, claims 53-80 will be pending. Claims 53-68, 71-73, and 76 have been amended; and new claims 79 and 80 have been added. Support for the new and amended claims can be found in the specification; therefore, no new matter has been added. (see, e.g., FIGS. 3A-5B, 6C-8D, and paragraph [0047] in the specification as filed). Reconsideration of the pending claims in view of the foregoing amendments and the following remarks is respectfully requested.

Priority

The Office Action indicted that Applicants' priority claim to prior filed Application No. 10/637,713 failed to provide adequate support or enablement under 35 U.S.C. § 112 first paragraph and therefore the effective filing date of the present application for the purpose of applying prior art would be the actual filing date of the present application, and not that of the prior filed '713 application. The Office Action stated that the prior filed '713 application disclosed a stent having a slot that can be expanded by a catheter if the stent is deployed in a location covering a side branch (Office Action, pages 2-3). The Office Action further stated that the prior filed '713 application discloses that a balloon dilation catheter may perform the slot expansion, but the '713 application did not disclose that it would be the same balloon that expanded the stent in the main branch or that it would be the same balloon that would position the additional stents in the side branch (Office Action, page 3). Applicants respectfully request reconsideration of the effective filing date of the instant application for at least the following reasons.

In addition to the reasons previously submitted by Applicants (see Amendment filed February 9, 2009), Applicants respectfully direct the Examiner's attention to MPEP 2164.01, which states in part:

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as *to enable one skilled*

in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, which postured the question: *is the experimentation needed to practice the invention undue or unreasonable?* That standard is still the one to be applied. Accordingly, even though the statute does not use the term “undue experimentation,” it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *A patent need not teach, and preferably omits, what is well known in the art.*

(*emphasis added* and citations omitted).

Per MPEP 2161.01 III., “USPTO personnel must establish on the record a reasonable basis for questioning the adequacy of the disclosure to enable a person of ordinary skill in the art to make and use the claimed invention without resorting to *undue experimentation.*” Applicants respectfully submit that no such reasonable basis has been, or can be, established to support the notion that one reasonably skilled in the art would have to resort to undue experimentation to realize that the delivery catheter disclosed in the ‘713 application (clearly disclosed for treating multiple lesions without requiring removal of the catheter from the body) could be used to perform the treatment method disclosed in the ‘713 application for treating a main vessel lesion and a bifurcation lesion, without intermediate removal.

Therefore, Applicants respectfully request that the effective filing date of the present application be modified to include the priority claim to the earlier filed ‘713 application, which was filed August 8, 2003.

Claim Rejections Under 35 U.S.C. §112

The Office Action rejects claims 63, 65, and 72 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for reciting “an expandable member.” In response, these claims have been amended to recite “the expandable member” as suggested. Accordingly, withdrawal of the rejection of these claims under 35 U.S.C. §112 is respectfully requested.

Claim Rejections Under 35 U.S.C. §103

The Office Action rejects claims 53-62, 64, 67-71, and 73-78 under 35 U.S.C. §103(a) as allegedly being obvious over *Chermoni* (U.S. Patent Pub. No.: 2002/0156496) in view of *Poncet* (U.S. Patent No.: 5,833,694) and further in view of *Brucker et al.* (U.S. Patent Pub. No.: 2002/0193873). Such rejections are overcome for the reasons set forth below.

While Applicants respectfully disagree with the rejections and do not acquiesce to any reasoning provided in the Office Action, claims 53-68, 71-73 and 76 have been amended to expedite prosecution in the present case. As will be set forth below for each of the independent claims, the proposed combination of *Chermoni* in view of *Poncet* in further view of *Brucker* fails to disclose or suggest all elements recited in the claims, thereby precluding the establishment of a *prima facie* case of obviousness.

Independent Claim 53 (Rejected Dependent Claims 54-62 and 73-78)

Claim 53 recites:

A method of treating one or more lesions in a vessel, the vessel having a main branch and a side branch branching from the main branch at a bifurcation, the method comprising:

providing a plurality of stents comprising a first, second, and third stent unconnected with each other;

positioning a delivery catheter in the main branch, the delivery catheter having an expandable member disposed thereon, wherein at least two of the stents are positionable over the expandable member in direct engagement with one another when unexpanded;

radially expanding the expandable member thereby radially expanding the first stent and the second stent concurrently in the main branch;

positioning the delivery catheter in the side branch; and

radially expanding the expandable member thereby radially expanding the third stent in the side branch,

wherein the delivery catheter remains in the vessel between radially expanding the first and second stents and the third stent.

(*emphasis added*)

The proposed combination of *Chermoni* in view of *Poncet* in further view of *Brucker* at least fails to disclose the above-emphasized elements. *Chermoni* discloses a catheter configured to carry one or more stents and having an inflatable balloon for expanding a stent surrounding the balloon. The catheter has a positioner for moving the one or more stents relative to the balloon from a first position in which a stent does not surround the balloon to a second position in which the stent surrounds the balloon. Also disclosed is a method for deploying a stent at a desired location in the vascular system. (*Chermoni* abstract) While *Chermoni* represents a considerable advancement in the art, *Chermoni* fails to disclose a method that includes *positioning a delivery catheter in the main branch, the delivery catheter having an expandable member disposed thereon, wherein at least two of the stents are positionable over the expandable member in direct engagement with one another when unexpanded; and radially expanding the expandable member thereby radially expanding the first stent and the second stent concurrently in the main branch* as recited in claim 53.

Poncet at least fails to disclose the above-noted elements that are missing from *Chermoni*. *Poncet* discloses a stent assembly and method of use in which self-expanding stents are sequentially deployed. (*Poncet* title and abstract). In *Poncet*, individual self-expanding stents are sequentially deployed as the constraint of sheath 10 is removed via movement of the sheath 10 relative to the stents. (See FIG. 1 through FIG. 3). As such, *Poncet* at least fails to disclose the above-noted steps recited in claim 53 that are missing from *Chermoni* (... *expanding the expandable member thereby radially expanding the first stent and the second stent concurrently in the main branch...*).

Brucker fails to disclose all of the above-noted elements that are missing from *Chermoni* and *Poncet*. *Brucker* discloses systems for delivering a bifurcated stent to a bifurcation site that comprise catheters and/or bifurcated stents delivered therefrom. (*Brucker* abstract) The stent disclosed in *Brucker* comprises a single scaffold 14 expandable to define a single opening 16 through the wall 18 of the stent body 12. (see, e.g., FIGS. 1, 2, and 7). In *Brucker*, individual stents are sequentially deployed. (see, e.g., FIGS. 18-20; paragraphs [0081]

through [0084]). As such, *Brucker* at least fails to disclose the above-noted elements recited in claim 53 that are missing from the proposed combination of *Chermoni* in view of *Poncet* (... *expanding the expandable member thereby radially expanding the first stent and the second stent concurrently in the main branch...*).

Thus, the proposed combination of *Chermoni* in view of *Poncet* in further view of *Brucker* fails to disclose all elements recited in claim 53. Accordingly, claim 53 is not rendered obvious by such a combination. Claims 54-62 and 73-78 depend from claim 53 and are allowable over the proposed combination for at least this reasons, as well as on their own merits. For example, claim 55 recites, in part, *wherein each of the first and second stents comprises a plurality of circumferentially and longitudinally arranged openings in a sidewall thereof, each opening of the plurality expandable to allow the deployment of a stent therethrough*. No such stents are disclosed in the cited references. Accordingly, Applicants respectfully request withdrawal of the rejections of claims 53-62 and 73-78 under 35 U.S.C. §103(a), and that these claims be allowed.

Independent Claim 64 (Rejected Dependent Claims 67-71)

Claim 64 recites certain elements similar to elements recited in claim 53. As such, for the reasons discussed above with regard to claim 53, the propose combination of *Chermoni* in view of *Poncet* in further view of *Brucker* fails to disclose a method including *positioning a delivery catheter in the first branch, the delivery catheter having an expandable member disposed, wherein at least two of the stents are positionable over the expandable member in direct engagement with one another when unexpanded; and radially expanding the expandable member thereby radially expanding the first stent and the second stent concurrently in the first branch, a portion of at least one of the first stent or the second stent being disposed across the bifurcation* as recited in claim 64. Accordingly, for the reasons set forth above with respect to claim 53, claim 64 is not rendered obvious by the proposed combination of references.

Claims 67-71 depend from claim 64 and are allowable over the proposed combination for at least this reason, as well as on their own merits. Accordingly, applicants

respectfully request withdrawal of the rejections of claims 64, and 67-71 under 35 U.S.C. §103(a), and that claims 64 and 67-71 be allowed.

The Office Action rejects claims 66-68 under 35 U.S.C. §103(a) as allegedly being obvious over *Chermoni* in view of *Brucker* as applied to claim 64 above, and further in view of *Loos et. al.* (U.S. Patent No.: 6,579,309). (The Office Action actually states “[c]laims 14-16 are rejected. Applicants are assuming that the rejections apply to claims 66-68, which correspond to canceled claims 14-16.) Such rejections are overcome for the reasons set forth below.

Claims 66-68 depend from claim 64. The rejections of claims 66-68 are premised on the proposed combination of *Chermoni* in view of *Brucker* disclosing all elements recited in claim 64, with the additional elements recited in claims 66-68 being obvious in further view of *Loos*. However, as discussed above, the proposed combination of *Chermoni* in view of *Brucker* fails to disclose all elements of claim 64. *Loos* discloses a stent for implantation in the region of vessel branchings. The *Loos* stent includes at least one branching portion which is provided to open a passage into the branch vessel. (*Loos* abstract) *Loos*, however, fails to provide the above-emphasized and discussed claim 64 elements that are missing from the proposed combination of *Chermoni* in view of *Brucker*. (...expanding the expandable member thereby radially expanding the first stent and the second stent concurrently in the first branch...).

Thus, claims 66-68 are not rendered obvious by the proposed combination of *Chermoni* in view of *Brucker*, and further in view of *Loos*. Accordingly, Applicants respectfully request withdrawal of the rejections of claims 66-68 under 35 U.S.C. §103(a), and that these claims be allowed.

The Office Action rejects claims 63, 65, and 72 under 35 U.S.C. §103(a) as allegedly being obvious over *Chermoni* in view of *Poncet* and further in view of *Brucker* as applied to claims 53 and 64 above, and further in view of *Shaknovich* (U.S. Patent No.: 5,807,398). Such rejections are overcome for the reasons set forth below.

Claim 63 depends from claim 53. And claims 65 and 72 depend from claim 64. The rejections of claims 63, 65, and 72 are premised on the proposed combination of *Chermoni* in view of *Poncet* and further in view of *Brucker* disclosing all elements recited in claims 53 and 64, with the additional elements recited in claims 63, 65, and 72 being obvious in further view of *Shaknovich*. However, as discussed above, the proposed combination of *Chermoni* in view of *Poncet* and further in view of *Brucker* fails to disclose all elements of claims 53 and 64. *Shaknovich* discloses a stent delivery system that includes a tubular stent delivery catheter comprising an expandable balloon segment, onto which a stent can be mounted in a contracted conformation. (*Shaknovich* abstract) *Shaknovich*, however, fails to provide the above-emphasized and discussed claim 53 (and claim 64) elements that are missing from the proposed combination of *Chermoni* in view of *Poncet* and further in view of *Brucker* (...*expanding the expandable member thereby radially expanding the first stent and the second stent concurrently...*). In contrast, *Shaknovich* discloses the deployment of a single stent at a time. Moreover, claim 72 recites, in part, *wherein each of the first and second stents comprises a plurality of circumferentially and longitudinally arranged sidewall openings, each opening of the plurality expandable to allow the deployment of a stent therethrough*. No such stents are disclosed in the cited references.

Thus, claims 63, 64, and 72 are not rendered obvious by the proposed combination of *Chermoni* in view of *Poncet* and further in view of *Brucker*, and further in view of *Shaknovich*. Accordingly, Applicants respectfully request withdrawal of the rejections of claims 63, 64, and 72 under 35 U.S.C. §103(a), and that these claims be allowed.

New Claims 79 and 80

Claim 79 depends from claim 53 and is allowable for at least this reason, as well as on its own merits. Similarly, claim 80 depends from claim 64 and is likewise allowable. Examination and allowance of claims 79 and 80 is respectfully requested.

Appl. No. 10/814,593
Arndt. dated January 8, 2010
Reply to Office Action of September 8, 2009

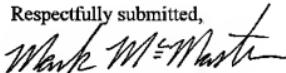
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,



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